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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,429	08/29/2001	Jorge H. Capdevila	22000.0110U2	7467

7590 02/25/2004

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EXAMINER

VOGEL, NANCY S

ART UNIT PAPER NUMBER

1636

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/942,429

Applicant(s)

CAPDEVILA ET AL.

Examiner

Nancy Vogel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-38 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40-43 is/are allowed.
- 6) ☒ Claim(s) 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/13/02 & 7/18/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1-43 are pending in the case. Receipt of Information Disclosure Statements on 12/13/02 and 7/8/02 is acknowledged.

### ***Election/Restrictions***

Applicant's election with traverse of Group XXII, and species Cyp4A11/W126 -> R, in the response filed 1/12/04 is acknowledged. The traversal is on the ground(s) that a serious burden has not been shown, specifically, that the Examiner has not shown that the search and examination of the entire application cannot be made without serious burden. Applicants state that the Groups I-XII and XIX-XXII, and Groups XIII-XVIII are all in the same class and can be readily searched together. This is not found persuasive because in the area of biotechnology, the search of non-patent literature is a major portion of the required search for proper examination, and therefore the fact that classification is the same does not rule out a burdensome search. Furthermore, the examiner has set out the reasons for the restriction in the previous Office action.

It is noted that applicant's traversal regarding the species election has been found convincing and the subject matter of claims 39-43 has been examined.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper submitted 1/12/04.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 39 is rejected under 35 U.S.C. 102(b) as being anticipated by Imaoka et al. (DNA Cell. Biol. 12(10):893-899 (1993) (cited by applicants)).

Imaoka et al. disclose a method comprising detecting a mutant Cyp 4A11 polypeptide or a mutated Cyp 4A11 nucleic acid in a subject, i.e. Cyp4A11v (see abstract, page 894, second col., last paragraph).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is based on the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description published in the Federal Register (Volume 66, Number 4, Pages 1099-1111).

Claim 39 is drawn to a method of identifying a subject having an increased susceptibility for developing hypertension, comprising detecting a mutant Cyp4A11 polypeptide or a mutated Cyp4A11 nucleic acid in the subject. The specification has defined mutant Cyp4A11 polypeptide or nucleic acid to refer to a polypeptide or nucleic acid having a sequence which differs from the normal wild-type Cyp4A11 nucleic acid or polypeptide (see page 36 of the specification). Claim 39 is a genus claim in terms of a method of identifying a subject having an increased susceptibility for developing hypertension comprising detecting any mutant of Cyp4A11 polypeptide or nucleic acid; the claims encompass a broad class of methods detecting a polypeptide or nucleic acid which may be virtually any sequence. The disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the methods of detecting all encompassed polypeptide or nucleic acid variants of Cyp4A11 which would indicate increased susceptibility for developing hypertension. While the specification provides general information regarding the sequence of the Cyp4A11 polypeptide and nucleic acid sequence, there is no structure function analysis of said polypeptide or nucleic acid sequence to provide guidance on the regions which, when altered, would result in an increased susceptibility to hypertension. The disclosure of 4 individual amino acids out of the full length polypeptide (over 500 amino acids in length), does not provide

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sufficient guidance in this matter. Therefore, the specification does not describe the claimed method in such full, clear, concise and exact terms so as to indicate that Applicant had possession of the method at the time of filing the present application. Thus, the written description requirement has not been satisfied.


Claims 40-43 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NTV

  
REMY YUCEL, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

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2/17/04